Notice of Allowability	Application No.	Applicant(s)	
	09/856,417	JOSSIFOFF, AZARIAH	
	Examiner	Art Unit	
	Alton N. Pryor	1616	

-- ***The MAILING DATE of this communication appears on the cover sheet with the correspondence address--***

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to *11/28/05*.

2. ☐ The allowed claim(s) is/are *52-54,106-108,113-123 (claims renumbered 1-17 respectively)*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 11/26/05;03/01/02
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney P. Ludwig on 2/27/06.

The application has been amended as follows:

The claim version below replaces all previous versions of the claims. Claims not included in this version are cancelled.

52. A method of delivering progesterone to a female patient, comprising placing in the vagina of said patient a tablet ~~comprising micronized~~ consisting of progesterone as the active ingredient, ~~a non-effervescent~~ pharmaceutically acceptable excipients or diluents, and an effervescent, and retaining said tablet in ~~said~~ the vagina for a time efficacious to deliver said progesterone to said patient.

53. A method according to claim 52, wherein ~~said tablet contains at least 50 mg of micronized~~ the progesterone in said tablet is present in an amount of at least 50 mg.

54. A method according to claim 53, wherein said placing of tablet is effected as part of a twice-daily dosing regimen.

106. A method of delivering progesterone to a female patient, comprising placing in the vagina of said patient a tablet consisting of progesterone, a pharmaceutically acceptable excipient or diluent, and an effervescent, wherein said tablet is prepared by the steps of:

(i) mixing water with ~~micronized~~ progesterone to obtain wetted ~~micronized~~ progesterone in the absence of ~~a~~ pharmaceutically acceptable excipients or diluents; and drying said wetted ~~micronized~~ progesterone to form dry ~~micronized~~ progesterone;

(ii) mixing said dry ~~micronized~~ progesterone with

(a) a pharmaceutically acceptable ~~non effervescent~~ excipients or diluents and

(b) an effervescent to form a mixture; and

(iii) forming the tablet by direct compaction of said mixture,

and retaining said tablet in said vagina until the tablet dissolves, wherein the tablet ~~having~~ provides a T_{max} upon ~~disintegration~~ dissolution of ~~at least~~ about three hours. ~~; and retaining said tablet in said vagina for a time efficacious to deliver said progesterone to said patient~~.

107. A method according to claim 106, wherein ~~said tablet contains at least 50 mg. of~~ the progesterone in said tablet is present in an amount of at least 50 mg.

108. A method according to claim 106, wherein said placing of said tablet is effected as part of a twice daily dosing regiment.

113. The method of claim 53, wherein the ~~tablet contains about 50 mg of~~ progesterone in said tablet is present in an amount of at least about 50 mg.

114. The method of claim 52, wherein the ~~tablet contains about 100 mg of~~ progesterone in said tablet is present in an amount of at least about 100 mg.

115. The method of claim 52, wherein the effervescent in the tablet is present in an amount of ~~comprises~~ about 5% to about 12% by weight of the tablet.

116. The method of claim 115, wherein the effervescent in the tablet is present in an amount of ~~comprise~~ about 8% by weight of the tablet.

117. The method of claim 52, wherein said placing of said tablet is effected as part of a twice-daily dosing regimen.

118. The method of claim 52, wherein the progesterone is micronized progesterone.

119. The method of claim 106, wherein the progesterone is micronized progesterone.

120. The method of claim 106, wherein the progesterone in said tablet is present in an amount of ~~contains~~ about 100 mg ~~of progesterone~~.

121. A method of delivering progesterone to a female patient, which method comprises

(a) placing in the vagina of the patient a vaginal tablet consisting of micronized progesterone as the active ingredient, pharmaceutically acceptable excipients or diluents, and an effervescent; and

(b) permitting the tablet to dissolve in the vagina,

the tablet providing a T_{max} of about 3 hours upon dissolution.

122. A method of delivering progesterone to a female patient, comprising placing in the vagina of the patient a tablet consisting essentially of micronized progesterone, colloidal anhydrous silica, maize starch, povidone, lactose, adipic acid, sodium bicarbonate, magnesium stearate, and sodium lauryl sulfate.

123. The method of claim 122, wherein the tablet\ consists essentially of ~~contains~~ about 8 wt. % dry micronized progesterone, about 0.2 wt. % colloidal anyhdrous silica, about 16.8 wt. % maize 1500 starch, about 4.0 wt. % povidone 30, about 60.8 wt. % lactose, about 4.5 wt. % adipic acid, about 3.4 wt. % sodium bicarbonate, about 1.8 wt. % magnesium stearate, and about 0.4 wt. % sodium lauryl sulfate.

The following is an examiner's statement of reasons for allowance: The closest prior art (US '211 and US '277) does not teach or suggest the instant invention. US '277 teaches a method of administering progesterone to promote fertilization, whereas, US '211 teaches a method of administering a composition comprising an effervescent and a spermatocide to prevent fertilization. Therefore, it would have not been obvious to one having ordinary skill in the art to combine the references since their utility is opposite. In addition, the "consisting essentially of" language would exclude the inclusion of the spermatocide from the instant invention.

Sherman et al (USPN 4310510) teaches that a pharmaceutically acceptable carrier for progesterone is an effervescent type suppository. However, Sherman teaches against a solid form of the progesterone and effervescent such as a tablet. For this reason Sherman would not make instant tablet (solid form) obvious.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alton Pryor
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